

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AMGEN INC.,

Plaintiff,

v.

AMNEAL PHARMACEUTICALS LLC,
et al.,

Defendants.

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C.A. No. 16-853 (MSG)
CONSOLIDATED



**AMGEN'S ANSWERING BRIEF IN OPPOSITION TO SUN'S
MOTION TO ENFORCE THE PARTIES' SETTLEMENT AGREEMENT**

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TABLE OF CONTENTS

	Page
I. FACTUAL BACKGROUND.....	3
A. The Sun Agreement	3
B. Teva’s At Risk Launch	7
II. ARGUMENT	9
A. The Court Lacks Subject Matter Jurisdiction to Decide Sun’s Motion	9
B. The Sun Agreement [REDACTED]	10
1. Legal Standards.....	10
2. [REDACTED]	11
3. [REDACTED] [REDACTED]	12
(a) [REDACTED]	13
(b) [REDACTED]	14
4. [REDACTED] [REDACTED] Support Amgen’s Interpretation of the Sun Agreement.....	17
C. Discovery and an Evidentiary Hearing Are Not Necessary.....	19
III. CONCLUSION.....	20

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>Aetna Life Ins. Co. v. Haworth</i> , 300 U.S. 227 (1937).....	10
<i>Armstrong World Indus., Inc. by Wolfson v. Adams</i> , 961 F.2d 405 (3d Cir. 1992).....	9
<i>Cipla Ltd. et al. v. Amgen Inc. et al.</i> , C.A. No. 19-44(LPS)	2
<i>Eagle Indus., Inc. v. DeVilbiss Health Care, Inc.</i> , 702 A.2d 1228 (Del. 1997)	11, 17
<i>First Data Corp. v. Inselberg</i> , 870 F.3d 1367 (Fed. Cir. 2017).....	9
<i>Flast v. Cohen</i> , 392 U.S. 83 (1968).....	9
<i>GMG Capital Inv., LLC v. Athenian Venture P’rs I, L.P.</i> , 36 A.3d 776 (Del. 2012)	11
<i>Hendrickson v. United States</i> , 791 F.3d 354 (2d Cir. 2015).....	9
<i>Kokkonen v. Guardian Life Ins. Co. of Am.</i> , 511 U.S. 375 (1994).....	9
<i>Maya Swimwear Corp. v. Maya Swimwear, LLC</i> , 855 F. Supp. 2d 229 (D. Del. 2012).....	10
<i>MedImmune, Inc. v. Genentech, Inc.</i> , 549 U.S. 118 (2007).....	10
<i>MicroStrategy, Inc. v. Acacia Research Corp.</i> , C.A. No. 5735–VCP, 2010 WL 5550455 (Del. Ch. Dec. 30, 2010).....	10, 11
<i>Parker-Hannifin Corp. v. Schlegel Elec. Materials, Inc.</i> , 589 F. Supp. 2d 457 (D. Del. 2008).....	11
<i>Rohm and Hass Elec. Materials, LLC v. Honeywell Int’l, Inc.</i> , C.A. No. 06-297, 2009 WL 1033651 (D. Del. Apr. 16, 2009).....	11

<i>S'holder Representative Servs. LLC v. Gilead Scis., Inc.</i> , C.A. No. CV 10537-CB, 2017 WL 1015621 (Del. Ch. Mar. 15, 2017), <i>aff'd</i> , 177 A.3d 610 (Del. 2017)	19
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Amgen Inc. (“Amgen”) hereby opposes Sun Pharmaceutical Industries Ltd., Sun Pharma Global FZE, and Sun Pharmaceutical Industries, Inc.’s (collectively, “Sun”) “Motion to Enforce the Parties’ Settlement Agreement.” [REDACTED] Sun entered into a litigation settlement agreement with Amgen on October 24, 2017 (“the Sun Agreement”) [REDACTED], and exited this consolidated patent infringement action early, avoiding potentially costly discovery and trial. In exchange, Sun agreed that [REDACTED]

[REDACTED]

[REDACTED]

After this Court entered a judgment of non-infringement as to another ANDA filer, Watson Laboratories, Inc. (“Watson”), and Amgen appealed that decision, Watson’s affiliate Teva Pharmaceuticals USA, Inc. (“Teva”) launched its product at risk on December 28, 2018. On January 2, 2019, Amgen and Teva entered into a settlement agreement [REDACTED]

[REDACTED]

[REDACTED] Contrary to the plain language of the Sun Agreement [REDACTED]

[REDACTED] Sun now argues that [REDACTED]

[REDACTED]

[REDACTED]. Sun’s motion should be denied for at least two reasons.

First, Sun’s motion is styled as a “motion to enforce the parties’ settlement agreement,” but Sun does not allege that Amgen has breached the settlement agreement or ask the Court to order Amgen to perform any acts. Nor does Sun cite any authority for the relief it is seeking from the Court. Rather, Sun’s motion improperly seeks discovery and an advisory opinion on

the proper interpretation of the Sun Agreement. Sun can seek advice from this Court regarding the meaning of its settlement agreement (and obtain relevant discovery) only by filing a declaratory judgment action that adequately pleads facts sufficient to establish that this Court has jurisdiction over an actual ripe case or controversy between the parties, as another party has attempted to do through a declaratory judgment action (*see Cipla Ltd. et al. v. Amgen Inc. et al.*, 19-44(LPS)).¹ Sun's motion, therefore, should be denied for lack of subject matter jurisdiction.

Second, Sun grossly misreads the Sun Agreement. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] [REDACTED]

[REDACTED]

[REDACTED] This should end the inquiry.

Sun also distorts the Sun Agreement by introducing requirements that are not found in the plain language of the Sun Agreement. In particular, Sun argues that Amgen [REDACTED]

[REDACTED]

[REDACTED] Not so. [REDACTED]

[REDACTED]

[REDACTED] Even if Sun is correct (it is not)

[REDACTED]

[REDACTED]

[REDACTED] This common-sense interpretation is

¹ Amgen does not admit that Sun can plead sufficient facts to support a declaratory judgment action against Amgen.

supported by the plain terms of the Sun Agreement. And to the extent there is any alleged ambiguity in the Sun Agreement, this interpretation is further supported and confirmed by the

██

██████████.

I. FACTUAL BACKGROUND

Amgen sued Sun on September 29, 2016, asserting that Sun's proposed Generic Cinacalcet Product² would infringe Amgen's U.S. Patent No. 9,375,405 ("the '405 patent") if marketed and sold in the United States. (*See* D.I. 1 in 16-cv-882.) On February 23, 2017, that lawsuit was consolidated into this action (Case No. 16-853), along with Amgen's lawsuits against several other generic drug manufacturers who filed ANDAs concerning generic cinacalcet HCl products.

A. The Sun Agreement

██

██

██, on October 24, 2017 Amgen and Sun entered into the Sun Agreement. (*See* Ex. A, Sun Agreement.) The Sun Agreement disposed of all claims between Amgen and Sun in the consolidated action and required the filing of a Stipulation of Dismissal and [Proposed] Order ("Stipulation"), which the Court entered on November 2, 2017. (*Id.* §2; D.I. 253.) Under the Stipulation, Sun admitted that its product infringed the '405 patent, and that the '405 patent was valid and enforceable. (D.I. 253.) The

² Where the definition of a particular term is not critical to the instant dispute, Amgen uses capitalized words to refer to specific terms defined in Section 1 of the Sun Agreement without providing the full definition of the term in this brief. These words are intended to have the same meanings as those provided in Section 1.

Stipulation enjoins Sun from selling its proposed Generic Cinacalcet Product “except to the extent specifically authorized in the Settlement Agreement.” (*Id.*)

The Sun Agreement [REDACTED]

[REDACTED] Pursuant to [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Consequently,

[REDACTED] Per the Sun Agreement, [REDACTED]

³ The ‘405 patent expires in September 2026 [REDACTED]

[illegible]

Thus, [REDACTED]

[REDACTED]⁴ [REDACTED] [REDACTED]
[REDACTED]
[REDACTED] [REDACTED]
[REDACTED]
[REDACTED] [REDACTED] [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED] [REDACTED] [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

However, [REDACTED]

[REDACTED]

Specifically, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

⁴ [REDACTED]
[REDACTED] [REDACTED]
[REDACTED]

[REDACTED] Here, the only Third Party that Launched (first sold) its Generic Cinacalcet Product At Risk was Teva. There is no dispute that Amgen entered into an agreement with Teva

[REDACTED] [REDACTED]
[REDACTED]

[REDACTED] This shows that the parties [REDACTED]

_____ . In fact, as discussed in more detail below, _____

B. Teva's At Risk Launch

On January 2, 2019, a mere two business days after Teva's At Risk Launch, Amgen and Teva agreed to settle their litigation pursuant to a settlement agreement (the "Amgen-Teva Agreement"), in which Teva agreed to cease selling its Generic Cinacalcet Product and pay a

specified amount to Amgen as a result of its At Risk Launch.⁵ Also on January 2, [REDACTED]

[REDACTED] Amgen sent a letter to Sun and its counsel notifying them that

[REDACTED] In essence, [REDACTED]

[REDACTED] As a result, Amgen notified Sun in its

[REDACTED] (*Id.*)

In response, Sun sent Amgen a letter on January 4 [REDACTED]

[REDACTED] Tellingly, Sun did not

⁵ See Ex. B, Amgen's Announcement of the Amgen/Teva/Watson Agreement, available at <https://wwwext.amgen.com/media/featured-news/2019/01/amgen-announced-today-that-it-has-resolved-its-ongoing-dispute-with-teva/>; Teva's Announcement of the Amgen/Teva/Watson Agreement, available at <http://ir.tevapharm.com/investors/press-releases/press-release-details/2019/Teva-and-Amgen-Resolve-Ongoing-Dispute-Over-Texas-Generic-Cinaclet-HCl-Product/default.aspx>.

II. ARGUMENT

A. The Court Lacks Subject Matter Jurisdiction to Decide Sun's Motion

This Court lacks subject matter jurisdiction to decide Sun's motion because the motion merely seeks an advisory opinion. "The judicial power of federal courts is constitutionally restricted to 'cases' and 'controversies.'" *Flast v. Cohen*, 392 U.S. 83, 94 (1968). Because federal courts can only hear cases and controversies, they do not have the power to issue purely advisory opinions. *Id.* at 95-96. Here, Sun's motion purports to be a motion to enforce a settlement agreement, which "is fundamentally a claim for breach of a contract." *Hendrickson v. United States*, 791 F.3d 354, 358 (2d Cir. 2015) (citing *Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 381 (1994)). But Sun does not allege that Amgen has breached any of its obligations under the Sun Agreement. Instead, Sun simply asks this Court to render an advisory opinion as to the proper interpretation of certain provisions of the Sun Agreement. Sun cites no authority suggesting that a federal court can issue such an advisory opinion on a motion to enforce a settlement agreement where no breach of the agreement is even alleged. *See Armstrong World Indus., Inc. by Wolfson v. Adams*, 961 F.2d 405, 410 (3d Cir. 1992) ("Article III, section 2 of the United States Constitution . . . stands as a direct prohibition on the issuance of advisory opinions"). Thus, this Court lacks subject matter jurisdiction to hear Sun's motion.

In addition, Sun's motion is not ripe for consideration. "A claim is not ripe for adjudication if it rests upon contingent future events that may not occur as anticipated, or indeed may not occur at all." *First Data Corp. v. Inselberg*, 870 F.3d 1367, 1375 (Fed. Cir. 2017) (quotations omitted). Sun asks the Court to declare that *if* it chooses to start selling its Generic Cinacalcet Product immediately, such sales **would be** authorized by the Sun Agreement. Sun does not allege that it intends to, and is in fact prepared to, start selling its generic product immediately. In fact, it is unclear if Sun will ever sell a Generic Cinacalcet Product in the United

States, let alone that it would do so immediately if this Court were to advise that it would not face contract liability if it were to launch based solely upon sales made by Teva's downstream distributors and resellers. Rather than even *attempt* to plead "a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment," *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007), Sun simply asks this Court to advise it of "what the law would be upon a hypothetical state of facts," *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 241 (1937). Thus, Sun's motion is not ripe because it seeks a declaration concerning purely speculative events that may or may not occur in the future.

B. The Sun Agreement [REDACTED]

To the extent the Court reaches the merits of Sun's motion, the Sun Agreement [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

1. Legal Standards

"State law governs the construction and enforcement of settlement agreements in federal court." *Maya Swimwear Corp. v. Maya Swimwear, LLC*, 855 F. Supp. 2d 229, 234 (D. Del. 2012). Here, the Sun Agreement provides that it "shall be governed and construed in accordance with the laws of the State of Delaware." (Ex. A, Sun Agreement § 8.3.) Delaware interprets settlement agreements according to traditional contract construction, which seeks "to determine the parties' shared intent, looking first at the relevant document, read as a whole, in order to divine that intent." *MicroStrategy, Inc. v. Acacia Research Corp.*, No. 5735-VCP, 2010 WL 5550455, *5 (Del. Ch. Dec. 30, 2010)(quotations omitted). The Court must be careful not to interpret the agreement in a manner that renders any provision "illusory or meaningless." *Id.*

If an agreement's language is "clear and unambiguous," the ordinary meaning or the parties' agreed-upon definition of that language will generally establish the parties' intent. *Id.* In such a case, "extrinsic evidence may not be used to interpret the intent of the parties, to vary the terms of the contract, or to create an ambiguity." *GMG Capital Inv., LLC v. Athenian Venture P'rs I, L.P.*, 36 A.3d 776, 783-84 (Del. 2012) (quoting *Eagle Indus., Inc. v. DeVilbiss Health Care, Inc.*, 702 A.2d 1228, 1232 (Del. 1997)). However, if a contract is ambiguous, the Court may consider extrinsic evidence, including evidence of prior agreements and communications of the parties as well as trade usage or course of dealing. *Eagle Indus.*, 702 A.2d at 1233.

In Delaware, the standard of review for settlement enforcement motions is similar to the standard for summary judgment motions. *Rohm and Hass Elec. Materials, LLC v. Honeywell Int'l., Inc.*, No. 06-297, 2009 WL 1033651, at *4 (D. Del. Apr. 16, 2009). Thus, Sun's enforcement motion should only be granted if the moving papers show that Sun is entitled to judgment as a matter of law. *See Parker-Hannifin Corp. v. Schlegel Elec. Materials, Inc.*, 589 F. Supp. 2d 457, 461 (D. Del. 2008).

2. [REDACTED]

Under any construction of the Sun Agreement, [REDACTED]

[REDACTED]

[REDACTED]. Teva Launched its product on December 28, 2018 [REDACTED]

[REDACTED]. Thus,

[REDACTED] [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]. It is undisputed that [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

3. [REDACTED]
[REDACTED]

Because it cannot [REDACTED], Sun resorts to arguing that [REDACTED]

[REDACTED]

[REDACTED].

Sun is wrong. [REDACTED]

[REDACTED]

[REDACTED].

Although Amgen generally agrees with Sun's characterization of what occurs during an At-Risk Launch, [REDACTED]

[REDACTED] It is true that generic manufacturers may sell more than the amount of product the market would normally absorb during a brief At Risk Launch; that a generic drug manufacturer might release product "in phase" by selling to an unrelated distributor; and that distributors in turn sell to other channels or outlets, whereby eventually the product may make its way to end users. (D.I. 437 at 5.) These are all common occurrences associated with At Risk Launches, and

Sun was aware of these types of occurrences when it negotiated the Sun Agreement. As set forth below, however, [REDACTED]

[REDACTED] In fact, Sun's declarant states that [REDACTED] (D.I. 437, Ex. G, Kuznetsov Decl. ¶5.) The Sun Agreement makes clear that [REDACTED]

(a) [REDACTED]

Sun contends that [REDACTED] (D.I. 437 at 2). This is manifestly incorrect. The Sun Agreement expressly provides that [REDACTED]

[REDACTED] According to the Sun Agreement's plain terms, [REDACTED]

[REDACTED] Indeed, as explained at pages 17-18 *infra*, [REDACTED]

[REDACTED] Thus, [REDACTED]

[REDACTED]

[REDACTED]. The Sun Agreement [REDACTED]

[REDACTED]

[REDACTED] [REDACTED] [REDACTED]

[REDACTED] Again, [REDACTED]

[REDACTED]

[REDACTED] Consequently, [REDACTED]

[REDACTED].

Sun tries to confuse the issue by [REDACTED]

[REDACTED]. Yet the Sun Agreement

[REDACTED]. Contrary to Sun's assertions, [REDACTED]

[REDACTED] (*See* Sun Br. at 8.) In fact, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] In either case, the fact remains that [REDACTED]

[REDACTED]

[REDACTED]

(b) [REDACTED]

Sun further contends that, [REDACTED]

[REDACTED]

[REDACTED] (Sun Br. at 7.) According to Sun, [REDACTED]

[REDACTED]

[REDACTED] (*Id.* at 7-9.) Sun's

argument is plainly incorrect; the express terms of the Sun Agreement [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

As discussed above,

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Here, contrary to Sun's arguments,

[REDACTED]

[REDACTED]

[REDACTED]

In this case,

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Thus, Amgen

[REDACTED]

[REDACTED].

Contrary to Sun's arguments,

[REDACTED]

[REDACTED]

[REDACTED]

Nor does the Agreement anywhere state

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED].

That this is precisely the result that the parties contemplated and bargained for is

[REDACTED]

Indeed,

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED] Specifically, [REDACTED]

[REDACTED]

[REDACTED] [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED].

Sun's argument that [REDACTED]

[REDACTED] is

also untenable. First, as discussed above, [REDACTED]

[REDACTED]. And Sun has pointed to nothing in

the Settlement Agreement that suggests [REDACTED]

[REDACTED]. [REDACTED]

[REDACTED]

[REDACTED]

Thus, [REDACTED]

[REDACTED] Although Sun now argues that [REDACTED]

[REDACTED]

[REDACTED] Sun cannot now ask the Court to rewrite the Sun Agreement. In fact, [REDACTED]

[REDACTED]

**4. [REDACTED] Support
Amgen's Interpretation of the Sun Agreement**

To the extent that the Court finds the Sun Agreement ambiguous as to whether Sun is permitted to enter the market due to Amgen's failure to "police" the market, the Court may then consider extrinsic evidence to determine the proper interpretation of the agreement. *Eagle Indus.*, 702 A.2d at 1233. Amgen and Sun [REDACTED]

[REDACTED] These [REDACTED] demonstrate that Amgen's interpretation of the agreement is correct. They also show that [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] [REDACTED] [REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED].

The parties' [REDACTED] show that [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Sun cannot now argue that

[REDACTED]

[REDACTED] *See S'holder Representative Servs. LLC v. Gilead Scis., Inc.*, No. CV 10537-CB, 2017 WL 1015621, at *1 (Del. Ch. Mar. 15, 2017), *aff'd*, 177 A.3d 610 (Del. 2017) (rejecting party's proposed contract interpretation, in which *disease-subgroup* level regulatory approval of drug would trigger milestone payment, where party's statements during negotiations showed party clearly intended that milestone payment would only be triggered by a *disease-level* regulatory approval). As such, ample extrinsic evidence supports Amgen's interpretation that [REDACTED]

[REDACTED] 2. Accordingly, [REDACTED]

[REDACTED]

C. Discovery and an Evidentiary Hearing Are Not Necessary

Sun requests that the Court grant limited, expedited discovery and an evidentiary hearing as to (a) the content of [REDACTED] and (b) the nature of [REDACTED]. (Sun Br. at 10.) As to the first topic, it cannot be reasonably disputed that Teva Launched its product At-Risk on December 28. [REDACTED]

[REDACTED] Nothing contained in the Amgen-Teva agreement can

change the fact that [REDACTED]

[REDACTED] Regarding the second topic, as discussed above, [REDACTED]

[REDACTED] As such, no discovery on this point [REDACTED]

[REDACTED] In sum, neither discovery nor a hearing is needed for either of these topics and the Court should deny Sun's requests.

III. CONCLUSION

For the foregoing reasons, Amgen respectfully requests that this Court DENY Sun's Motion to Enforce the Parties Settlement Agreement and DENY Sun's requests for limited, expedited discovery and an evidentiary hearing.

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April 11, 2019

CERTIFICATE OF SERVICE

I hereby certify that on April 11, 2019, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on April 11, 2019, upon the following in the manner indicated:

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